4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2021-N-1030]

Brenda K. Marmas: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Brenda K. Marmas for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Ms. Marmas engaged in a pattern of importing or offering for import misbranded drugs (i.e. in an amount, frequency, or dosage that is inconsistent with her personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. Ms. Marmas was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of December 12, 2021 (30 days after receipt of the notice), Ms. Marmas had not responded. Ms. Marmas' failure to respond and request a hearing constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500, or at https://www.regulations.gov.

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM-4029), Office of Strategic Planning and Operational Policy, Office of Regulatory

Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240 402-8743, or at debarments@fda.hhs.gov.

SUPPLEMENTARY INFORMATION

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if FDA finds, as required by section 306(b)(3)(D) of the FD&C Act, that the individual has engaged in a pattern of importing or offering for import misbranded drugs (i.e. in an amount, frequency, or dosage that is inconsistent with personal or household use by the importer), and the shipments are not designated in an entry in an authorized electronic data exchange system as products regulated by FDA.

After an investigation, FDA discovered that Ms. Marmas has engaged in numerous instances of importing or offering for import misbranded drugs; all the parcels containing the misbranded drugs serving as the basis for this action, described in further detail below, were intercepted by FDA at either the John F. Kennedy International Airport (JFK), San Francisco International Airport (SFO), or Chicago International Airport Mail Facilities (MF) and were addressed to Ms. Marmas at an address connected to her.

On or about March 3, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,000 tablets of levofloxacin IP and was a misbranded drug for a number of reasons: (1) the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label; (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act (21 U.S.C. 360(j)); and (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act. FDA also determined that another product

contained in this parcel was 900 tablets of moxifloxacin hydrochloride and was a misbranded drug for a number of reasons: (1) the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label; (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act; and (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act. Both products were refused entry on March 26, 2020.

On or about March 3, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 300 tablets of azithromycin IP and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label. FDA also determined that one of the products contained in this parcel was 600 tablets of azithromycin IP and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label. Both products were refused entry on March 25, 2020.

On or about July 8, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. FDA determined that the product contained in this parcel was 2,304 capsules of azithromycin 250 milligrams (mg) and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label and the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on August 5, 2020.

On or about July 17, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 300 tablets of amoxicillin 875 mg and was a misbranded drug for multiple reasons: (1) the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label; (2)

the article had been determined to lack adequate directions for use; and (3) the drug was not included in a list required by section 510(j) of the FD&C Act. FDA also determined that one of the products contained in this parcel was 1,400 capsules of clindamycin 300 mg and was a misbranded drug because the article had been determined to lack adequate directions for use and the drug was not included in a list required by section 510(j) of the FD&C Act. Both products were refused entry on September 23, 2020.

On or about July 17, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 84 tablets of azithromycin 250 mg and was a misbranded drug for multiple reasons: (1) the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label; (2) the article had been determined to lack adequate directions for use; and (3) the drug was not included in a list required by section 510(j) of the FD&C Act. FDA also determined that one of the products contained in this parcel was 1,800 capsules of clindamycin 150 mg and was a misbranded drug because the article had been determined to lack adequate directions for use and because the drug was not included in a list required by section 510(j) of the FD&C Act. FDA also determined that one of the products contained in this parcel was 500 tablets of roxithromycin 150 mg and was a misbranded drug because the article had been determined to lack adequate directions for use and because the drug was not included in a list required by section 510(j) of the FD&C Act. All three products were refused entry on September 23, 2020.

On or about July 21, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. FDA determined that the product contained in this parcel was 2,520 capsules of fluconazole 200 mg and was a misbranded drug because the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act and because the drug was

not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on August 17, 2020.

On or about July 30, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. FDA determined that the product contained in this parcel was 2,000 capsules of doxycycline hyclate 100 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol "Rx only." The product was refused entry on October 5, 2020.

On or about July 30, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 500 capsules of amoxicillin trihydrate 500 mg and was a misbranded drug for multiple reasons: (1) the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label; (2) the article had been determined to lack adequate directions for use; and (3) the drug was not included in a list required by section 510(j) of the FD&C Act. FDA determined that one of the other products contained in this parcel was 2,000 capsules of clindamycin 300 mg and was a misbranded drug because the article had been determined to lack adequate directions for use and because the drug was not included in a list required by section 510(j) of the FD&C Act. FDA determined that one of the other products contained in this parcel was 300 tablets of amoxicillin/clavulanic acid 875 mg/125 mg and was a misbranded drug for multiple reasons: (1) the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label; (2) the article had been determined to lack adequate directions for use; and (3) the drug was not included in a list required by section 510(j) of the FD&C Act. All three products were refused entry on October 9, 2020.

On or about July 31, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 576 capsules of

azithromycin 250 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and the article had been determined to lack adequate directions for use. FDA determined that the other product contained in this parcel was 1,600 tablets of clarithromycin 500 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. Both products were refused entry on September 4, 2020.

On or about August 13, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at SFO MF that was addressed to her. FDA determined that the product contained in this parcel was 2,860 capsules of doxycycline hyclate 100 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only.” The product was refused entry on October 6, 2020.

On or about September 30, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at Chicago International Airport MF that was addressed to her. FDA determined that the product contained in this parcel was 1,000 tablets of amoxycillin and potassium clavulanate IP and was a misbranded drug because the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act and because the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on October 26, 2020.

On or about October 2, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 230 tablets of LQUIN levofloxacin and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and the article had been determined to lack adequate directions for use. FDA determined that the other product contained in this parcel was 129 tablets of AZICIP azithromycin and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label and

the article had been determined to lack adequate directions for use. Both products were refused entry on October 28, 2020.

On or about October 16, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at Chicago International Airport MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,500 capsules of amoxicillin and was a misbranded drug for multiple reasons: (1) the required label or labeling was determined to not be in English in violation of § 201.15(c)(1) (21 CFR 201.15(c)(1)); (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act; (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act; and (5) the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label. FDA determined that the other product contained in this parcel was 1,600 tablets of FLOXCIPRO 250 ciprofloxacin and was a misbranded drug for multiple reasons: (1) the required label or labeling was determined to not be in English in violation of § 201.15(c)(1); (2) the article had been determined to lack adequate directions for use; (3) the drug was not included in a list required by section 510(j) of the FD&C Act; (4) the drug was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 510 of the FD&C Act; and (5) the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label. Both products were refused entry on December 3, 2020.

On or about November 16, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 300 tablets of AZICIP azithromycin and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label. FDA determined that the other product contained in this parcel was 1,000 tablets of CIPRODAC ciprofloxacin and was a

misbranded drug because the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. Both products were refused entry on December 10, 2020.

On or about December 15, 2020, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,000 capsules of cephalexin IP 500 mg (CEPHADEX 500) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. FDA determined that one of the products contained in this parcel was 30 capsules of vancomycin hydrochloride IP 250 mg (VANLID 250) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. FDA determined that one of the other products contained in this parcel was 250 tablets of trimethoprim and sulphamethoxazole IP (BACTRIM DS) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. All three products were refused entry on January 19, 2021.

On or about April 23, 2021, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 1,000 capsules of RESTECLIN 500 (tetracycline) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. FDA determined that one of the products contained in this parcel was 400 tablets of RIFAGUR 400 (rifaximin) and was a misbranded drug as the article was determined to be a prescription drug but did not include the symbol “Rx only” on its label. Both products were refused entry on May 18, 2021.

On or about May 26, 2021, Ms. Marmas offered for import a parcel intercepted and processed by FDA at JFK MF that was addressed to her. This parcel contained multiple products. FDA determined that one of the products contained in this parcel was 500 tablets of amoxycillin and potassium clavulanate IP and was a misbranded drug because the article was determined to

be a prescription drug but did not include the symbol "Rx only" on its label. The product was refused entry on June 25, 2021. FDA determined that the other product contained in this parcel was 300 tablets of azithromycin IP 500 mg and was a misbranded drug because the article was determined to be a prescription drug but did not include the symbol "Rx only" on its label. This product was refused entry on June 24, 2021.

On or about July 15, 2021, Ms. Marmas offered for import a parcel intercepted and processed by FDA at Chicago International Airport MF that was addressed to her. FDA determined that the product contained in this parcel was 500 tablets of amoxycillin and potassium clavulanate IP; CIPMOX CV-625 and was a misbranded drug because the article had been determined to lack adequate directions for use and because the drug was not included in a list required by section 510(j) of the FD&C Act. The product was refused entry on August 13, 2021.

As a result of this pattern of importing or offering for import misbranded drugs (i.e. in an amount, frequency, or dosage that is inconsistent with her personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA, in accordance with section 306(b)(3)(D) of the FD&C Act, FDA sent Ms. Marmas, by certified mail on November 3, 2021, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States.

In proposing a debarment period, FDA weighed the considerations set forth in section 306(c)(3) of the FD&C Act that it considered applicable to Ms. Marmas' pattern of conduct and concluded that her conduct warranted the imposition of a 5-year period of debarment.

The proposal informed Ms. Marmas of the proposed debarment and offered her an opportunity to request a hearing, providing 30 days from the date of receipt of the letter in which to file the request, and advised her that failure to request a hearing constituted a waiver of the opportunity for a hearing and of any contentions concerning this action. Ms. Marmas received the proposal and notice of opportunity for a hearing on November 12, 2021. Ms. Marmas failed

to request a hearing within the timeframe prescribed by regulation and has, therefore, waived her opportunity for a hearing and waived any contentions concerning her debarment. (21 CFR part 12).

II. Findings and Order

Therefore, the Assistant Commissioner, Office of Human and Animal Food Operations, under section 306(b)(3)(D) of the FD&C Act, under authority delegated to the Assistant Commissioner, finds that Ms. Brenda K. Marmas has engaged in a pattern of importing or offering for import misbranded drugs (i.e. in an amount, frequency, or dosage that is inconsistent with her personal or household use) that are not designated in an authorized electronic data interchange system as products regulated by FDA. FDA finds that this pattern of conduct should be accorded a debarment period of 5 years as provided by section 306(c)(2)(A)(iii) of the FD&C Act.

As a result of the foregoing finding, Ms. Marmas is debarred for a period of 5 years from importing or offering for import any drug into the United States, applicable (see DATES). Pursuant to section 301(cc) of the FD&C Act (21 U.S.C. 331(cc)), the importing or offering for import into the United States of any drug or controlled substance by, with the assistance of, or at the direction of Ms. Marmas is a prohibited act.

Any application by Ms. Marmas for termination of debarment under section 306(d)(1) of the FD&C Act should be identified with Docket No. FDA-2021-N-1030 and sent to the Dockets Management Staff (see ADDRESSES). The public availability of information in these submissions is governed by 21 CFR 10.20(j).

Publicly available submissions will be placed in the docket and will be viewable at http://www.regulations.gov or at the Dockets Management Staff (see ADDRESSES) between 9 a.m. and 4 p.m., Monday through Friday.

Dated: February 3, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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